

/I B/ PTO/SB/08 Equivalent

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Multiple sheets used when necessary) | Application No.      | <del>10/373,364</del> 10/572,404         |
|   | Filing Date          | March 27, 2006                           |
|   | First Named Inventor | Kuhara, et al.                           |
|   | Art Unit             | Unknown                                  |
|   | Examiner             | Unknown                                  |
| SHEET 1 OF 1  | Attorney Docket No.  | <del>TOYA108.014APC</del> TOYA108.013APC |

| U.S. PATENT DOCUMENTS /I B./ |          |   |                                |                               |  |
|------------------------------|----------|---|--------------------------------|-------------------------------|--|
| Examiner Initials            | Cite No. | Document Number<br>Number - Kind Code (if known)<br>Example: 1,234,567 B1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant | Pages, Columns, Lines Where<br>Relevant Passages or Relevant<br>Figures Appear |
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| FOREIGN PATENT DOCUMENTS |          |  |                                |                                      |  |                        |
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| Examiner Initials        | Cite No. | Foreign Patent Document<br>Country Code-Number-Kind Code<br>Example: JP 1234567 A1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant        | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear | T <sup>1</sup>         |
| /I B./                   |          | JP 2001-503430   | 03/13/01                       | Wisconsin Alumni Research Foundation |  | PCT 1 <sup>st</sup> Pg |
| /I B./                   |          | JP 2002-515893   | 05/28/02                       | Pharming B.V.                        |  | PCT 1 <sup>st</sup> Pg |
| /I B./                   |          | JP 2001-149069   | 06/05/01                       | Inst of Physical & Chemical Res      |  | Abstract               |
| /I B./                   |          | WO 98/19675  | 05/14/98                       | Wisconsin Alumni Research Foundation |  |                        |
| /I B./                   |          | WO 98/33509  | 08/06/98                       | Pharming BIV.                        |  |                        |
|                          |          |  |                                |                                      |  |                        |
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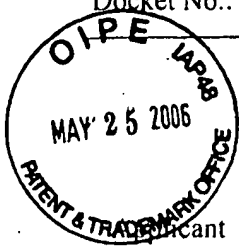
| NON PATENT LITERATURE DOCUMENTS |          |   |                |
|---------------------------------|----------|---|----------------|
| Examiner Initials               | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
| /I B./                          |          | Porgador, et al. "Natural Killer Cell Lines Kill Autologous $\beta_2$ -Microglobulin-Deficient Melanoma Cells: Implications for Cancer Immunotherapy," <i>Proc. Natl. Acad. Sci., USA</i> , Vol. 94, pp. 13140-13145, 1997.                                     |                |
| /I B./                          |          | <i>Molecular Medicine</i> , Vol. 39, pp. 238-246, 2002.   | Partial        |
| /I B./                          |          | <i>Molecular Medicine</i> , Vol. 40, pp. 186-193, 2003.   | Partial        |
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| Examiner Signature /Layla Bland/ | Date Considered 01/23/2008 |
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\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.



/L.B./

## INFORMATION DISCLOSURE STATEMENT

Applicant : Higuchi, et al.  
App. No : 10/572,404  
Filed : March 16, 2006  
For : DRUG AND METHOD FOR  
PROLIFERATING NATURAL KILLER  
CELLS  
Examiner : Unknown  
Art Unit : Unknown

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application is a PTO/SB/08 Equivalent listing 8 references to be considered by the Examiner. These eight references are provided..

WO 98/19675 is submitted as the English language equivalent for JP 2001-503430.

WO 98/33509 is submitted as the English language equivalent for JP 2002-515893.

All references include at least a partial translation in the English language.

This Information Disclosure Statement is being filed within three months of the filing date of the application no fee is required.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON &amp; BEAR, LLP

Dated:

May 22, 2006

By:

Che S. Chereskin

Che Swyden Chereskin, Ph.D.

Registration No. 41,466

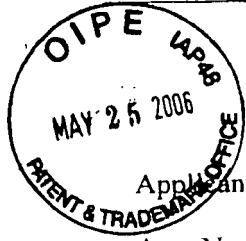
Agent of Record

Customer No. 20,995

(949) 760-0404

/L.B./

Please Direct All Correspondence to Customer Number 20995



**TRANSMITTAL LETTER**  
**INFORMATION DISCLOSURE STATEMENT**

Applicant : Higuchi, et al.  
App. No : 10/572,404  
Filed : March 16, 2006  
For : DRUG AND METHOD FOR  
PROLIFERATING NATURAL KILLER  
CELLS  
Examiner : Unknown  
Art Unit : Unknown

**CERTIFICATE OF MAILING**

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

May 22, 2006

(Date)

*Che S. Chereskin*

Che Swyden Chereskin, Ph.D., Reg. No. 41,466

**Mail Stop Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Dear Sir:

Enclosed for filing in the above-identified application are:

- (X) An Information Disclosure Statement and PTO/SB/08 equivalent listing 8 references for consideration. Eight references are enclosed.
- (X) The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Account No. 11-1410.
- (X) Return prepaid postcard.

*Che S. Chereskin*

Che Swyden Chereskin, Ph.D.

Registration No. 41,466

Agent of Record

Customer No. 20,995

(949) 760-0404

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br><i>(Multiple sheets used when necessary)</i> | Application No.      | Unknown         |
|  | Filing Date          | Herewith        |
|  | First Named Inventor | Higuchi, et al. |
|  | Art Unit             | Unknown         |
| Examiner   |                      | Unknown         |
| SHEET 1 OF 1   | Attorney Docket No.  | TOYA108.013APC  |

| U.S. PATENT DOCUMENTS |          |  |                                |                               |  |
|-----------------------|----------|--|--------------------------------|-------------------------------|--|
| Examiner Initials     | Cite No. | Document Number<br><i>Number - Kind Code (if known)</i><br>Example: 1,234,567 B1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant | Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear |
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| /L.B./                   |          | JP 2003-286185  | 10/07/03                       | Daily Foods KK                |  | Abstract       |
|                          |          |   |                                |                               |  |                |
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| /L.B./                          |          | Abou Zeid, "Chemical and Biological Study of the Leaves of Some <i>Musa</i> Species," <i>Egypt. J. Pharm Sci.</i> Vol. 39, Nos. 4-6, pp. 379-398, 1998.   |                |
| /L.B./                          |          | Can, et al. "Effect of <i>Aloe vera</i> Leaf Gel and Pulp Extracts on the Liver in Type-II Diabetic Rat Models," <i>Biol. Pharm. Bull.</i> , Vol. 27, No. 5, pp. 694-698, 2004.   |                |
| /L.B./                          |          | Yeh, et al. "Systematic Review of Herbs and Dietary Supplements for Glycemic Control in Diabetes," <i>Diabetes Care</i> , Vol. 26, No. 4, pp. 1277-1294, April, 2003.   |                |
| /L.B./                          |          | International Search Report completed June 22, 2005.  |                |
|                                 |          |   |                |

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|---|---------------------------------|
| Examiner Signature      /Layla Bland/   | Date Considered      01/23/2008 |
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T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Multiple sheets used when necessary)

SHEET 1 OF 3

|                      |                 |
|----------------------|-----------------|
| Application No.      | 10/572,404      |
| Filing Date          | March 16, 2006  |
| First Named Inventor | Higuchi, et al. |
| Art Unit             | Unknown         |
| Examiner             | Unknown         |
| Attorney Docket No.  | TOYA108.013APC  |

## U.S. PATENT DOCUMENTS

| Examiner Initials | Cite No. | Document Number<br>Number - Kind Code (if known)<br>Example: 1,234,567 B1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant  | Pages, Columns, Lines Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-------------------|----------|---|--------------------------------|--------------------------------|--|
| /L.B./            |          | 4,598,069   | 07/01/86                       | Toyo Yakushoku Kogyo Co., Ltd. |  |
| /L.B./            |          | 2002/0048613  | 04/25/02                       | Romanczyk, et al.              |  |
| /L.B./            |          | 2003/0207818  | 11/06/03                       | Jia, et al.                    |  |
|                   |          |   |                                |                                |  |

## FOREIGN PATENT DOCUMENTS

| Examiner Initials | Cite No. | Foreign Patent Document<br>Country Code-Number-Kind Code<br>Example: JP 1234567 A1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant      | Pages, Columns, Lines<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>1</sup>         |
|-------------------|----------|--|--------------------------------|------------------------------------|---|------------------------|
| /L.B./            |          | WO 97/16438  | 05/09/97                       | Merck & Co., Inc.                  |   |                        |
| /L.B./            |          | WO 99/19505  | 04/22/99                       | Univera Pharmaceuticals, Inc.      |   |                        |
| /L.B./            |          | JP 11-511482   | 10/15/99                       | Merck & Co., Inc.                  |   | PCT 1 <sup>st</sup> Pg |
| /L.B./            |          | JP 2001-520019   | 10/30/01                       | Univera Pharmaceuticals, Inc.      |   | PCT 1 <sup>st</sup> Pg |
| /L.B./            |          | JP 2003-095941   | 04/03/03                       | Ito En Ltd                         |   | Abstract               |
| /L.B./            |          | JP 2002-371003   | 12/26/02                       | Kikkoman Corp                      |   | Abstract               |
| /L.B./            |          | JP 05-247086   | 09/24/93                       | Kowa Kagaku Kogyo KK               |   | Abstract               |
| /L.B./            |          | JP 2002-205949   | 07/23/02                       | Yuusu Techno Corporation:KK        |   | Abstract               |
| /L.B./            |          | JP 2003-048837   | 02/21/03                       | Inst of Physical & Chemical Res    |   | Abstract               |
| /L.B./            |          | JP 10-330266   | 12/15/98                       | Kotarou Kanpo Seiyaku KK           |   | Abstract               |
| /L.B./            |          | JP 09-040689   | 02/10/97                       | Nippon Flour Mills Co Ltd          |   | Abstract               |
| /L.B./            |          | JP 55-153719   | 11/29/80                       | Okayasu Shoten:KK                  |   | Abstract               |
| /L.B./            |          | JP 59-027824   | 02/14/84                       | Sankyo Co Ltd                      |   | Abstract               |
| /L.B./            |          | JP 59-036623   | 02/28/84                       | Zenyaku Kogyo KK                   |   | Abstract               |
| /L.B./            |          | JP 59-073600   | 04/25/84                       | Okayasu Shoten:KK                  |   | Abstract               |
| /L.B./            |          | JP 2003-277269   | 10/02/03                       | Univ Nihon                         |   | Abstract               |
| /L.B./            |          | JP 50-160262   | 12/25/75                       | Riken Vitamin Oil Kabushiki Kaisha |   | Claim                  |
| /L.B./            |          | JP 08-208495   | 08/13/96                       | Nonogawa Shoji KK                  |   | Abstract               |
| /L.B./            |          | JP 10-120576   | 05/12/98                       | Kureha Chem Ind Co Ltd             |   | Abstract               |
| /L.B./            |          | JP 10-045604   | 02/17/98                       | Kureha Chem Ind Co Ltd             |   | Abstract               |
| /L.B./            |          | JP 10-036271   | 02/10/98                       | Kureha Chem Ind Co Ltd             |   | Abstract               |

Examiner Signature /Layla Bland/

Date Considered 01/23/2008

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(Multiple sheets used when necessary) | Application No.      | 10/572,404      |
|   | Filing Date          | March 16, 2006  |
|   | First Named Inventor | Higuchi, et al. |
|   | Art Unit             | Unknown         |
|   | Examiner             | Unknown         |
| SHEET 2 OF 3  | Attorney Docket No.  | TOYA108.013APC  |

| FOREIGN PATENT DOCUMENTS |          |  |                                |                               |   |                |
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| /L.B./                   |          | JP 09-059298   | 03/04/97                       | Yurika KK                     |   | Abstract       |
| /L.B./                   |          | JP 60-214741   | 10/28/85                       | Toya Yakushiyoku Kogyo KK     |   | Abstract       |
|                          |          |  |                                |                               |   |                |

| NON PATENT LITERATURE DOCUMENTS |          |   |  |  |  |                |
|---------------------------------|----------|---|--|--|--|----------------|
| Examiner Initials               | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |  |  |  | T <sup>1</sup> |
| /L.B./                          |          | Nippon Rinsho, Vol. 1, No. 748, pp. 615-617, 1999   |  |  |  | Partial        |
| /L.B./                          |          | Nippon Rinsho, Vol. 2, No. 808, pp. 405-409, 2002   |  |  |  | Partial        |
| /L.B./                          |          | "The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus," <i>The New England Journal of Medicine</i> , Vol. 329, No. 14, pp. 977-986, 1993                          |  |  |  |                |
| /L.B./                          |          | Bunyaphatsara, et al. "Antidiabetic Activity of <i>Aloe vera</i> L. Juice II. Clinical Trial in Diabetes Mellitus Patients in Combination with Glibenclamide," <i>Phytomedicine</i> , Vol. 3, No. 3, pp. 247-248, 1996.   |  |  |  |                |
| /L.B./                          |          | Okyar, et al. "Effect of <i>Aloe Vera</i> Leaves on Blood Glucose Level in Type I and Type II Diabetic Rat Models," <i>Phytotherapy Research</i> , Vol. 15, pp. 157-161, 2001   |  |  |  |                |
| /L.B./                          |          | Beppu, et al. "Hypoglycaemic and Antidiabetic Effects in Mice of <i>Aloe arborescens</i> Miller var. <i>natalensis</i> Berger," <i>Phytotherapy Research</i> , Vol. 7, pp. S37-S42, 1993  |  |  |  |                |
| /L.B./                          |          | Yongchaiyudha, et al. "Antidiabetic Activity of <i>Aloe vera</i> L. Juice. I. Clinical Trial in New Cases of Diabetes Mellitus," <i>Phytomedicine</i> , Vol. 3, No. 3, pp. 241-243, 1996  |  |  |  |                |
| /L.B./                          |          | Koo. "Aloe Vera: Antiulcer and Antidiabetic Effects," <i>Phytotherapy Research</i> , Vol. 8, pp. 461-464, 1994.   |  |  |  |                |
| /L.B./                          |          | Akihisa T., Matsumoto T., <i>Yukagaku</i> , Vol. 36, pp. 301-319, 1987 with relevance explanation.  |  |  |  | Partial        |
| /L.B./                          |          | Afzal, et al. "Identification of Some Prostanoids in <i>Aloe vera</i> Extracts," <i>Planta Med</i> , Vol. 57, pp. 38-40, 1991.  |  |  |  |                |
| /L.B./                          |          | Ghannam, et al. "The Antidiabetic Activity of Aloes: Preliminary Clinical and Experimental Observations," <i>Hormone Research</i> , Vol. 24, pp. 288-294, 1986.   |  |  |  |                |
| /L.B./                          |          | Ajabnoor. "Effect of Aloes on Blood Glucose Levels in Normal and Alloxan Diabetic Mice," <i>Journal of Ethnopharmacology</i> , Vol. 28, pp. 215-220, 1990.  |  |  |  |                |
| /L.B./                          |          | Grover, et al. "Medicinal Plants of India with Anti-Diabetic Potential," <i>Journal of Ethnopharmacology</i> , Vol. 81, pp. 81-100, 2002.   |  |  |  |                |
| /L.B./                          |          | Bolkent, et al. "Effect of <i>Aloe vera</i> (L.) Burm. fil. Leaf Gel and Pulp Extracts on Kidney in Type-II Diabetic Rat Models," <i>Indian Journal of Experimental Biology</i> , Vol. 42, pp. 48-52, 2004.   |  |  |  |                |
| /L.B./                          |          | Hikino, et al. "Isolation and Hypoglycemic Activity of Arbores A and B, Glycans of <i>Aloe arborescens</i> var. <i>natalensis</i> Leaves," <i>Int. J. Crude Drug Res</i> , Vol. 24, No. 4, pp. 183-186, 1986  |  |  |  |                |

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|  | First Named Inventor | Higuchi, et al. |
|  | Art Unit             | Unknown         |
| (Multiple sheets used when necessary)                    | Examiner             | Unknown         |
| SHEET 3 OF 3   | Attorney Docket No.  | TOYA108.013APC  |

| NON PATENT LITERATURE DOCUMENTS |             |   |                |
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| Examiner<br>Initials            | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
| /L.B./                          |             | International Search Report dated June 22, 2005.  |                |

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## NON PATENT LITERATURE DOCUMENTS

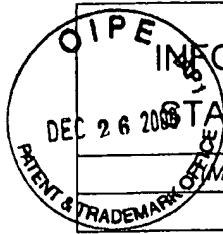
| Examiner<br>Initials | Cite<br>No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
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| /L.B./               |             | Bunyapraphatsara, et al. "Antidiabetic Activity of <i>Aloe vera</i> L. Juice II. Clinical Trial in Diabetes Mellitus Patients in Combination with Glibenclamide," <i>Phytomedicine</i> , Vol. 3, No. 3, pp. 245-248, 1996.                                      |                |
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|   |               |                 |            |
|---|---------------|-----------------|------------|
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## FOREIGN PATENT DOCUMENTS

| Examiner Initials | Cite No. | Foreign Patent Document<br>Country Code-Number-Kind Code<br>Example: JP 1234567 A1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant | Pages, Columns, Lines<br>Where Relevant Passages or<br>Relevant Figures Appear | T <sup>1</sup> |
|-------------------|----------|--|--------------------------------|-------------------------------|--|----------------|
| /L.B./            |          | JP 9-224588  | 09/02/97                       | Mitsubishi Chem Corp          |  | Abstract       |
| /L.B./            |          | JP 10/36283  | 02/10/98                       | Ichimaru Pharcos Co Ltd       |  | Abstract       |
| /L.B./            |          | JP 1-312978  | 12/18/89                       | Kobayashi Shiro               |  | Abstract       |
|                   |          |  |                                |                               |  |                |
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## NON PATENT LITERATURE DOCUMENTS

| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>1</sup> |
|-------------------|----------|---|----------------|
| /L.B./            |          | Notice of Reason for Rejection issued to a corresponding Japanese application and dated October 3, 2006   |                |
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| Examiner Signature  | /Layla Bland/ | Date Considered | 01/23/2008 |
| *Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |               |                 |            |

T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

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|---|----------------------|---------------------|----------------|
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br>(Multiple sheets used when necessary)<br>SHEET 1 OF 1 | Application No.      | 10/572,404          |                |
|   | Filing Date          | March 16, 2006      |                |
|   | First Named Inventor | Higuchi, et al.     |                |
|   | Art Unit             | Unknown             |                |
|   | Examiner             | Unknown             |                |
|   |                      | Attorney Docket No. | TOYA108.013APC |

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| Examiner<br>Initials  | Cite<br>No. | Document Number<br>Number - Kind Code (if known)<br>Example: 1,234,567 B1 | Publication Date<br>MM-DD-YYYY | Name of Patentee or Applicant | Pages, Columns, Lines Where<br>Relevant Passages or Relevant<br>Figures Appear |
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| Examiner<br>Initials     | Cite<br>No. | Foreign Patent Document<br>Country Code-Number-Kind Code<br>Example: JP 1234567 A1 | Publication<br>Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant | Pages, Columns, Lines<br>Where Relevant Passages or<br>Relevant Figures Appear | T <sup>1</sup>                                  |
| /L.B./                   |             | JP 9-224588  | 09/02/97                          | Mitsubishi Chem Corp             |  | Abstract &<br>Partial<br>English<br>Translation |
| /L.B./                   |             | JP 10/36283  | 02/10/98                          | Ichimaru Pharcos Co Ltd          |  | Abstract &<br>Partial<br>English<br>Translation |
| /L.B./                   |             | JP 1-312978  | 12/18/89                          | Kobayashi Shiro                  |  | Abstract &<br>Partial<br>English<br>Translation |
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| /L.B./                          |             | Notice of Reason for Rejection issued to a corresponding Japanese application and dated October 3, 2006 (originally in Japanese, but with English translation provided)   | ✓              |
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| Examiner Signature  | /Layla Bland/ | Date Considered | 01/23/2008 |
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T<sup>1</sup> - Place a check mark in this area when an English language Translation is attached.

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b> | Application No.      | 10/572,404          |                |
|  | Filing Date          | March 16, 2006      |                |
|  | First Named Inventor | Higuchi, et al.     |                |
|  | Art Unit             | 1614                |                |
| (Multiple sheets used when necessary)                    |                      | Examiner            | Unknown        |
| SHEET 1 OF 1   |                      | Attorney Docket No. | TOYA108.013APC |

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| Examiner Initials     | Cite No. | Document Number<br>Number - Kind Code (if known)<br>Example: 1,234,567 B1 | Issue Date<br>MM-DD-YYYY | Name of Patentee or Applicant | Pages, Columns, Lines Where<br>Relevant Passages or Relevant<br>Figures Appear |
| /L.B./                |          | 5,494,907   | 02/27/96                 | Nique, et al.                 |  |
| /L.B./                |          | 5,556,845   | 09/17/96                 | Nique, et al.                 |  |
| /L.B./                |          | 5,679,788   | 10/21/97                 | Nique, et al.                 |  |
| /L.B./                |          | 5,705,494   | 01/06/98                 | Nique, et al.                 |  |
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| /L.B./                   |          | RU 2 192 876   | 11/20/02                          | Vasil'evna, et al.               |  | Abstract       |
| /L.B./                   |          | RU 2 140 423   | 10/27/99                          | Nikke, et al.                    |  | Abstract       |
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